UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LARRY ENRIQUEZ, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. NABRIVA THERAPEUTICS PLC, TED SCHROEDER, GARY SENDER, and JENNIFER SCHRANZ, Defendants.	**Case No. 19-cv-04183-VM** **JURY TRIAL DEMANDED**

CONSOLIDATED CORRECTED AMENDED CLASS ACTION COMPLAINT

Lead Plaintiff Jonathan Schaeffer ("Plaintiff"), individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's Consolidated Corrected Amended Class Action Complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Nabriva Therapeutics plc ("Nabriva" or the "Company"), analysts' reports and advisories about the Company, information about the Company's Contract Manufacturing Organizations, and other information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons who purchased or otherwise acquired Nabriva common stock between January 4, 2019 through April 30, 2019, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and its senior officers. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

2. Nabriva is a biopharmaceutical company based in Ireland that sought to develop anti-infective agents to treat serious infections. In July 2018, Nabriva merged with Zavante Therapeutics Inc. ("Zavante"), a biopharmaceutical company based in San Diego, California that developed an injectable antibiotic known as CONTEPO™ (fosfomycin) that seeks to treat complicated urinary tract infections ("cUTIs").

3. During the Class Period, Nabriva only had two product candidates that had been submitted to the FDA for marketing approval. CONTEPO's New Drug Application ("NDA") was the first to be submitted to the FDA in October 2018, and the Company led the market to believe that CONTEPO would receive marketing approval in 2019. During the Class Period, the Company did not generate any revenues from product sales, and did not expect to generate any revenues unless CONTEPO or the other drug candidate obtained marketing approval.

4. Because the clinical trials for CONTEPO were touted as a success before the merger, Nabriva led the market to believe that FDA approval for CONTEPO was imminent in 2019. For example, on January 4, 2019, Nabriva issued a press release hailing the FDA's

acceptance of CONTEPO's NDA as "another major milestone," and boasted that the submission was "supported by a robust data package," including a successful clinical trial.

5. Unbeknownst to investors, however, Nabriva knew or recklessly disregarded that there were serious problems at the manufacturing plant where CONTEPO was produced. CONTEPO was manufactured by Ercros S.A. ("Ercros"), an industrial group based in Barcelona, Spain that produces basic chemicals, plastics and pharmaceutical compounds. Ercros established a plant in Aranjeuz, Spain that is primarily dedicated to the production of fosfomycin.

6. Between December 10, 2018 and December 14 2018, the FDA conducted an inspection of the plant in Aranjuez, Spain, and ultimately issued a Form 483 letter that identified a series of findings that described how the plant did not comply with Current Good Manufacturing Practices ("cGMP"). The FDA refuses to approve an NDA for a drug if the manufacturing facility where the drug is produced does not comply with cGMP. *See* 21 C.F.R. § 314.125 (13).

7. Defendant Ted Schroeder ("Schroeder") was the Chief Executive Officer ("CEO") of Zavante before Nabriva's merger with Zavante, and claimed that he brought ten employees from Zavante, who continued to exclusively focus on CONTEPO's NDA application. Nabriva also touted that it had a wealth of in-house knowledge and experience in the manufacturing process for CONTEPO, and affirmatively represented that it engaged third-party expert consultants to manage its relationship with Ercros. Moreover, Nabriva's contract supply agreement with Ercros contains multiple provisions that affirmatively required that Nabriva be immediately notified of any negative feedback from the FDA, including Form 483 inspection letters pertaining to any manufacturing deficiencies at the production facility in Aranjeuz, Spain. Accordingly, Defendants knew or recklessly disregarded, even before the January 4, 2019 press

release, that the FDA had already issued a Form 483 letter for cGMP violations at the production facility in Aranjuez, Spain.

8. Despite knowing that CONTEPO was produced in a manufacturing facility riddled with cGMP violations, Defendants misleadingly hyped the FDA's acceptance of the NDA submission for CONTEPO and boasted about the scientific data that supported the NDA submission, while omitting to tell investors that there were serious issues related to cGMP or the Form 483 letter that would delay approval of the NDA.

9. On March 12, 2019, the Company filed its Annual Report for the fiscal year that ended on December 31, 2018 ("2018 Form 10-K"), which failed to disclose to investors that the potential "risks" associated with the cGMP violations and the Form 483 letter, in fact, had already occurred, and would cause a delay in the approval of the NDA and commercialization of CONTEPO.

10. Indeed, the 2018 Form 10-K misleadingly stated that unidentified third party manufacturers *may* not receive regulatory approval of their manufacturing processes; *may* not produce sufficient quantities of CONTEPO at an acceptable quality; *may* not comply with cGMP; and *may* receive a Form 483 letter that *could* negatively impact Nabriva's development and commercialization efforts. Defendants knew or recklessly disregarded that each and every one of these alleged risks had already occurred when the Class Period began.

11. On April 30, 2019, Defendants were forced to disclose that the FDA had refused to approve the NDA for CONTEPO. The FDA's refusal was based on the cGMP violations that the FDA had found during its inspection of the production facility that manufactured CONTEPO.

12. On this news, Nabriva's share price declined $0.82 per share, or over 27%, to close at $2.17 on May 1, 2019, on heavy trading volume.

13. On August 16, 2019, Nabriva announced that it would resubmit the NDA for CONTEPO after it rectified the cGMP violations. The FDA extended the timeline for reviewing the NDA, which significantly delayed the prospect of approval for CONTEPO well beyond the projected date in 2019.

14. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market price of Nabriva common stock upon the disclosure and/or materialization of the risk that the FDA refused to approve the NDA for CONTEPO due to the cGMP violations, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

15. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and Section 27 of the Exchange Act.

17. Venue is proper in this Judicial District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b). Many of the acts and transactions that constitute the alleged violations of the law, including the dissemination to the public of materially false and misleading statements of fact, occurred in this District where the Company's securities traded on the NASDAQ Global Select Market ("NASDAQ-GS").

18. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of a national securities exchange located in this Judicial District.

PARTIES

19. Plaintiff acquired Nabriva common stock at artificially inflated prices during the Class Period and was damaged upon the disclosure and/or materialization of the risks concealed by Defendants' Class Period misrepresentations and omissions.

20. Defendant Nabriva is incorporated under the laws of Ireland with its executive offices located in Dublin, Ireland. The majority of the Company's employees are located in the United States with forty-seven employees based in the Company's office in King of Prussia, Pennsylvania. Nabriva's common stock trades on the NASDAQ-GS under the ticker symbol "NBRV."

21. Defendant Schroeder has served at all relevant times as the Company's CEO and Director.

22. Defendant Gary Sender ("Sender") has served at all relevant times as the Company's Chief Financial Officer ("CFO") and Executive Vice President.

23. Defendant Jennifer Schranz ("Schranz") has at all relevant times served as the Company's Chief Medical Officer ("CMO").

24. The Defendants referenced above in ¶¶ 21-23 are sometimes referred to herein collectively as the "Individual Defendants."

25. The Individual Defendants possessed the power and authority to control the contents of Nabriva's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of the Company's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with the Company, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to

and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

26. Nabriva describes itself as a biopharmaceutical company that develops anti-infective agents to treat serious infections. The Company was incorporated as a spin-off from Sandoz GmbH in October 2005. In 2014, the Company opened an office in the United States based in King of Prussia, Pennsylvania and completed an Initial Public Offering on the NASDAQ in 2015. In June 2017, the Company's headquarters were re-domiciled in Dublin, Ireland.

27. On July 24, 2018, the Company merged with Zavante in an all-stock deal. Zavante was a privately held clinical stage biopharmaceutical company based in San Diego, California that developed CONTEPO (fosfomycin) to treat infections caused by multi-drug resistant bacteria, including cUTIs. As part of the deal, Defendant Schroeder, the President and CEO of Zavante, became the new CEO of Nabriva. Outside the United States, fosfomycin has previously been approved for the treatment of a variety of indications.

28. In April 2017, Zavante had announced that CONTEPO met the primary endpoint of statistical non-inferiority in a Phase II/Phase III clinical trial known as ZEUS™ that enrolled patients with cUTIs, including Acute Pyelonephritis ("AP"). Based on the results of the ZEUS study, in October 2018, Nabriva submitted an NDA to the FDA that sought marketing approval of CONTEPO for the treatment of cUTIs, including AP in adults in the United States. The NDA was submitted pursuant to Section 505(b)(2) of the Food, Drug and Cosmetic Act of 1938 (hereafter "FDCA").

29. Under Section 505(b)(2) of the FDCA, an applicant can rely on the FDA's previous findings of safety and efficacy for a similar product or scientific literature that has already been published. In other words, Section 505(b)(2) allows an applicant to rely on clinical studies that were not conducted by the applicant, and authorizes the FDA to approve an NDA based on safety and efficacy data that were not developed by the applicant.

30. However, the FDA also requires that manufacturing facilities that produce the drug candidate comply with cGMP, and may refuse to approve an NDA if the manufacturing process does not comply with cGMP. *See* 21 C.F.R. § 314.125 (13).

31. On July 28, 2016, Zavante Laboratorios ERN, S.A. ("ERN"), a subsidiary of Zavante, and Ercros entered into an amended and restated three way agreement (the "three-way agreement") pursuant to which Zavante took *direct responsibility* for the manufacture and supply of CONTEPO in the United States, and relieved ERN's prior responsibility to provide any commercial product to Zavante. Defendant Schroeder executed the three-way agreement on behalf of Zavante.

32. Article 8 of the three-way agreement placed an affirmative duty on Zavante "to contract with one or more third party manufacturers to provide quantities of the Product required by Zavante for commercial sale in the [United States] and perform validation activities with respect thereto as required by the FDA, *and obtain FDA approval of such third party manufacturer's facilities and quality systems*." *See* three-way agreement at 6 (italics supplied).

33. Pursuant to Article 2 of the three-way agreement, Ercros manufactured CONTEPO as set forth in the Ercros-Zavante Supply Agreement that was also entered into on July 28, 2016, and executed by Defendant Schroeder on behalf of Zavante. Pursuant to the Ercros-Zavante Supply Agreement, Zavante had the sole responsibility "for filing all documents with all

Regulatory Authorities and taking any other actions that may be required for the receipt and/or maintenance of Regulatory Authority approval for" CONTEPO's NDA in the United States. *See* Article 11.7 of the Ercros-Zavante Supply Agreement at 12.

34. Nabriva, by virtue of its merger with Zavante, assumed the responsibilities, liabilities and obligations of Zavante under the Ercros-Zavante Supply Agreement and the three-way agreement.

The FDA Drug Approval Process

35. The FDA approval process of new or generic drug applications includes a substantive review of a manufacturer's compliance with the cGMP. An FDA inspector determines whether an applicant has the requisite facilities, equipment and ability to produce the drug that it intends to market to the public.

36. The failure to comply with cGMP renders a drug as adulterated under Section 501(a)(2)(B) of the FDCA and subjects the responsible entity to adverse regulatory action. *See* 21 C.F.R. § 210.1(b).

37. The FDA may refuse to approve an NDA if the "methods to be used in, and the facilities and controls used for, the manufacture, processing, packing, or holding of the drug substance or the drug product do not comply with the current good manufacturing practice regulations in parts 210 and 211" of the United States Code of Federal Regulations. *See* 21 C.F.R. § 314.125 (13). The Ercros-Zavante Supply Agreement specifically defined cGMP to mean the regulations contained in parts 210 and 211 of the United States Code of Federal Regulations. *See* Article 1 of the Ercros-Zavante Supply Agreement at 1.

CONTEPO's Production Facility Violated cGMP

38. The FDA conducted an inspection of the plant that manufactured CONTEPO between December 10, 2018 and December 14, 2018. On December 14, 2018, the FDA issued a Form 483 letter that was addressed and sent to Maria Carmen Cruzado, the Director of the Pharmaceutical Division at Ercros. Cruzado executed the three-way agreement and the Ercros-Zavante Supply Agreement on behalf of Ercros in July 2016, which required Ercros to notify Nabriva/Zavante of the FDA inspection and the Form 483 letter.

39. An FDA Form 483 letter is issued to a manufacturing facility at the end of an inspection if an FDA investigator has observed any conditions that may constitute violations of the FDCA or related federal statutes. Only significant conditions are noted on a Form 483 letter, which would indicate that a drug has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health. FDA Form 483 letters are discussed with management at the conclusion of an investigation, and companies are responsible to take corrective actions to rectify the regulatory violations observed at a manufacturing facility.

40. The Form 483 letter sent to Ercros identified a litany of regulatory violations at the production plant in Aranjeuz, Spain, and identified numerous manufacturing processes that did not comply with cGMP or were Out of Specifications ("OOS"), including:

- Drug batches of fosfomycin yielded results that were OOS due to inconsistent peak integrations, and further failed to meet the required reference standard. Although Ercros tested the batches again using a different methodology, the new method did not comply with Ercros' own Standard Operating Procedures ("SOP") or with cGMP.

- A manufacturing investigation to determine why batches of fosfomycin were OOS was purportedly conducted, but the investigation lacked evidence to support the root causes of the discrepancy. Although an attempt was made to process the batches again, Ercros did not implement or document a proper Corrective and Preventive Action Plan ("CAPA").
- Impurities were identified in certain batches of fosfomycin, but an investigation to determine the root cause of the impurities was inadequate. Ercros further failed to implement or document a proper CAPA to prevent the impurities in the future.
- Ercros failed to implement a process validation plan to test intra-batch variability, and thus ensure consistency between batches of fosfomycin.
- Ercros' quality control unit failed to place batches of fosfomycin on long-term stability to ensure longevity of the drug despite multiple attempts because the batches yielded results that were OOS. Moreover, Ercros failed to validate the process for current batch sizes.
- The electronic control system used for manufacturing fosfomycin was not adequately validated to allow batches to be properly tracked and audited. Nor were there adequate written SOP to review the electronic data before batches were recorded and released.
- During production, a series of alarms were triggered that went unaddressed, and Ercros failed to provide documentation on how to address the alarms and specify what actions needed to be taken by an operator in response to the alarms.
- There were no written SOP for storage or the time allowed between collection and testing for samples used to check for contamination. Ercros' quality control unit also failed to ensure that microorganisms used to test for contamination could be recovered from water samples after a certain specified amount of time.

- Ercros failed to clean, maintain and sanitize equipment and utensils used during the manufacturing process to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug. In fact, the FDA inspector observed visible flaws in the equipment that could alter the purity or the quality of the drug.
- Ercros failed to measure in-process checks of the manufacturing equipment to ensure they were calibrated and documented in accordance with its own SOP.

Defendants Knew or Recklessly Disregarded That the Production of CONTEPO Failed to Comply with cGMP

41. Nabriva is, reportedly, a small company with 110 employees around the world. At the time that Nabriva merged with Zavante, Defendant Schroeder described Zavante as a "pretty small company" with only ten employees who were all exclusively dedicated to working on CONTEPO's NDA application. He further represented that these same ten employees would remain committed to dedicating their time and resources towards CONTEPO's approval and commercialization at Nabriva. In fact, in the 2018 Form 10-K, Nabriva held itself out as having "significant in-house knowledge and experience in (i) the relevant chemistry associated with our product candidates; and (ii) the relevant manufacturing and supply chain processes associated with the commercial supply of our product candidates." *See* 2018 Form 10-K at 23. In addition, Nabriva affirmatively represented that it specifically engaged "third-party consultants[,] to assist in the management of our third-party manufacturers." *Id.*

42. Multiple provisions of the Ercros-Zavante Supply Agreement required that Nabriva/Zavante be immediately notified of any 483 letters or FDA communications regarding any FDA inspection of the production plant in Aranjeuz, Spain. For example, Article 10.6 of the Ercros-Zavante Supply Agreement required Ercros to "notify and, if applicable, provide copies of any notices of communication relating to the manufacture of [CONTEPO] or to any facility at

which [CONTEPO] is manufactured, including, but not limited to, any FDA FORM 483 or warning letter, promptly and not more than [**] after Ercros became aware of such inspection, investigation or other inquiry or communication and shall promptly thereafter provide to Zavante a written summary of all findings and corrective actions taken or planned by Ercros, including any written responses from Ercros to the FDA or other government agency."[1] *See* Article 10.6 of the Ercros-Zavante Supply Agreement at 10-11.

43. Similarly, Article 10.1.7 and 10.4 imposed a continuing obligation on Ercros to disclose to Nabriva any 483 letter received from the FDA in a timely fashion during the term of the Ercros-Zavante Supply Agreement. *Id.* at 10.

44. In addition, Article 10.9 of the Ercros-Zavante Supply Agreement required Ercros to immediately notify Nabriva of any information indicating that CONTEPO was not manufactured in accordance with the manufacturing specifications or in compliance with cGMP. *Id.* at 11.

45. Accordingly, Defendant Schroeder saw to it that Ercros was contractually obligated to immediately inform Zavante/Nabriva regarding any problems identified in any FDA inspection of the production plant in Aranjeuz, Spain. Indeed, the Defendants understood the significance of timely notification of any FDA communications regarding the manufacturing facility, as violations of cGMP would derail approval of the Company's first NDA and commercialization of what would have been its first and only product on the market. Moreover, Article 11.7 of the Ercros-Zavante Supply Agreement placed "sole responsibility" on Zavante/Nabriva regarding any action that "may be required for the receipt and/or maintenance of Regulatory Authority approval" of CONTEPO in the United States. *Id.* at 12.

[1] The double asterisks denote a redaction by Nabriva in its public filings.

Materially False and Misleading Statements Issued During the Class Period

46. The Class Period begins on January 4, 2019 when Nabriva issued a press release entitled "Nabriva Therapeutics Announces Acceptance of the New Drug Application for Intravenous CONTEPO™ to Treat [cUTIs] by FDA." In this press release, Defendant Schranz touted the NDA submission for CONTEPO as "another major milestone" for the Company, and boasted that CONTEPO was a "first-in-class" intravenous antibiotic. The January 4, 2019 press release also claimed that the NDA submission was supported by a "robust data package," and misleadingly claimed that "the FDA stated that no filing or potential review issue were identified."

47. On January 23, 2019, Defendant Schroeder spoke at a corporate analyst meeting. Defendant Schroeder made the following statements about the NDA submission for CONTEPO, saying:

> We've ***submitted New Drug Applications*** for both lefamulin for community-acquired pneumonia and ***for CONTEPO*** or IV fosfomycin for complicated urinary tract infections. . . . . And the data are solid for both products, and ***we think that they will not only win FDA approval but that they will be a significant additions to the antibiotic armamentarium in the United States***.

48. Defendants Schroeder later in the same conference reiterated:

> We have an April 30 PDUFA date for CONTEPO. We will launch CONTEPO shortly after approval[.]

49. The statements identified in paragraphs 46-48 were materially false and misleading when made because they omitted to disclose that (a) the facility where CONTEPO was manufactured had already been subject to a Form 483 letter from the FDA that identified violations of cGMP, (b) the nature of the cGMP violations at the facility that manufactured CONTEPO could, and ultimately did, result in the denial of CONTEPO's NDA, and (c) the FDA had identified a "review issue" for the NDA based on the findings in the Form 483 letter, not the NDA packet the FDA accepted as complete.

50. On March 12, 2019, Nabriva filed its 2018 Form 10-K with the SEC. The Individual Defendants signed and certified the 2018 Form 10-K pursuant to the Sarbanes Oxley Act of 2002. In the 2018 Form 10-K, the Defendants made the following materially false and misleading statements regarding the Company's ability to obtain marketing approval for and ultimately commercialize CONTEPO:

> The success of lefamulin and CONTEPO will depend on a number of factors, including the following:
>
> - establishing and maintaining arrangements with third-party manufacturers for commercial supply and receiving regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities;
>
> ****
>
> ***If we do not achieve one or more of these factors in a timely manner or at all**, **we could experience significant delays or an inability to successfully commercialize lefamulin for CABP or for any other indication or CONTEPO for cUTI**,* including AP or for any other indication, which would materially harm our business.

51. The statements identified in paragraph 50 were materially false and misleading when made because they failed to disclose that (a) the facility where CONTEPO was manufactured had already been subject to a Form 483 letter from the FDA that identified violations of cGMP, and (b) the nature of the cGMP violations at the facility that manufactured CONTEPO *would* cause a significant delay in seeking FDA approval for CONTEPO, and *would* adversely impact Nabriva's ability to successfully commercialize CONTEPO.

52. The 2018 Form 10-K further contained the follow materially false and misleading statements regarding the Company's reliance on third-party manufactures:

> Risks Related to Our Dependence on Third Parties

> Use of third parties to manufacture our product candidates ***may*** increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable quality or cost, which ***could*** delay, prevent or impair our development or commercialization efforts.

53. The statements identified in paragraph 52 were materially false and misleading when made because they omitted to disclose that prior to the Class Period (a) the facility where CONTEPO was manufactured had already been subject to a Form 483 letter from the FDA that identified violations of cGMP, and (b) the nature of the cGMP violations at the facility that manufactured CONTEPO *would* delay, prevent or impair Nabriva's attempt to develop and commercialize CONTEPO.

54. The 2018 Form 10-K specifically contained the following materially false and misleading statements regarding the Company's reliance on Ercros to produce the API mixture for CONTEPO, and Ercros' ability to comply with cGMP and other FDA requirements:

> We may be unable to maintain our current arrangements for commercial supply, or conclude agreements for commercial supply with additional third party manufacturers, or we may be unable to do so on acceptable terms. ***Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:***
>
> > • ***reliance on the third party for regulatory compliance and quality assurance;***
> >
> > • ***an event at one of our manufacturers or suppliers causing an unforeseen disruption of the manufacture or supply of our product candidates;***
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> ***
>
> ***Third-party manufacturers may not be able to comply with current good manufacturing practice, or cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal***

> ***prosecutions, any of which could significantly and adversely affect supplies of our product candidates and products.***

55. The statements identified in paragraph 54 were materially false and misleading when made because prior to the Class Period (a) the facility where CONTEPO was manufactured had already been subject to a Form 483 letter from the FDA that identified violations of cGMP, (b) the nature of the cGMP violations at the facility that manufactured CONTEPO *would* disrupt the production of CONTEPO, (c) a third-party manufacturer, Ercros, had already failed to comply with regulatory and quality assurance requirements, including cGMP, and (d) the failure to comply with cGMP and receipt of the Form 483 letter, as well as the nature of the violations themselves, *would* delay Nabriva's attempt to develop and commercialize CONTEPO.

56. The 2018 Form 10-K also contained the following materially false and misleading statements regarding the Company's ability to meet regulatory requirements:

> Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:
>
> - warning or untitled letters;
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> ***
>
> - refusal to approve pending applications or supplements to approved applications that we submit [.]

57. The statements identified in paragraph 56 were materially false and misleading when made because prior to the Class Period (a) the facility where CONTEPO was manufactured had already been subject to a Form 483 letter from the FDA that identified violations of cGMP, and (b) the failure to comply with cGMP and receipt of the Form 483 letter had already exposed CONTEPO's NDA to FDA refusal.

The Truth Begins to Emerge

58. On April 30, 2019, Nabriva announced in a press release that it had received a Complete Response Letter ("CRL") from the FDA for the NDA submitted to seek marketing approval of CONTEPO for the treatment of cUTI's, including AP. A CRL is a written communication from the FDA that describes the deficiencies that the agency has identified in a biologics license application that must be addressed before the application may be approved. The April 30, 2019 press release stated the following with respect to the contents of the CRL:

> The CRL requests that Nabriva address issues related to facility inspections and manufacturing deficiencies at one of Nabriva's contract manufacturers prior to the FDA approving the NDA.

59. On this news, Nabriva's share price declined $0.82 per share, or over 27%, to close at $2.17 per share on May 1, 2019, on heavy trading volume.

60. On August 16, 2019, Nabriva announced that it was required by the FDA to resubmit the NDA for CONTEPO after it took corrective actions to rectify the violations of cGMP. Any resubmission by Nabriva of the NDA was classified as Class 2, which significantly delayed the prospect of approval for CONTEPO. A resubmission of an application that is classified as Class 2 requires an applicant to start a new six-month review cycle that begins on the date that the FDA receives the resubmission. A resubmission dependent on the re-inspection of a manufacturing facility that does not comply with cGMP is classified as a Class 2 resubmission. To date, Nabriva has not submitted another NDA to the FDA for CONTEPO.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

61. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf all persons and entities that purchased or otherwise acquired Nabriva common stock between January 4, 2019 and April 30, 2019, both dates inclusive (the

"Class Period"), and were damaged thereby (the "Class"). Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

62. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Nabriva common stock was actively traded on the NASDAQ-GS. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Nabriva or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

63. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

64. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

65. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;

- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Nabriva;

- whether the Individual Defendants caused Nabriva to issue false and misleading statements during the Class Period;

- whether Defendants acted knowingly or recklessly in issuing false and misleading statements;

- whether the prices of Nabriva common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

66. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

67. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;

- Nabriva common stock is traded in an efficient market;

- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

- the Company traded on the NASDAQ-GS and was covered by multiple analysts;

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiff and members of the Class purchased, acquired and/or sold Nabriva common stock between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts materialized or were disclosed, without knowledge of the omitted or misrepresented facts.

68. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

69. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

70. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

71. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

72. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of common stock. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Nabriva

common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Nabriva common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

73. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the materially misleading statements described above that were designed to influence the market for Nabriva securities. The statements described above were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Nabriva's products and business prospects.

74. Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

75. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Nabriva, the Individual Defendants had knowledge of the details of Nabriva's internal affairs.

76. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of Nabriva's public statements. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Nabriva's business, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading statements, the market price of Nabriva common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Nabriva's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Nabriva common stock at artificially inflated prices and relied upon the price of the common stock, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

77. During the Class Period, Nabriva common stock traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Nabriva common stock at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said common stock, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Nabriva common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Nabriva common stock declined

upon public disclosure or materialization of the facts alleged herein to the injury of Plaintiff and Class members.

78. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

79. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure or materialization that the Company had been disseminating misleading statements to the investing public regarding its ability to develop and commercialize CONTEPO.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)

80. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

81. During the Class Period, the Individual Defendants participated in the operation and management of Nabriva, and conducted and participated, directly and indirectly, in the conduct of Nabriva's business affairs. Because of their senior positions, they knew the adverse non-public information that rendered Nabriva's public statements false and misleading.

82. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Nabriva's products and results of operations, and to correct promptly any public statements issued by Nabriva which had become materially false or misleading.

83. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the Company's statements, which Nabriva disseminated in the marketplace during the Class Period concerning Nabriva's products and business. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Nabriva to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Nabriva within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Nabriva common stock.

84. Each of the Individual Defendants, therefore, acted as a controlling person of Nabriva. By reason of their senior management positions and/or being directors of Nabriva, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Nabriva to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Nabriva and possessed the power to control the specific activities, which comprise the primary violations about which Plaintiff, and the other members of the Class complain.

85. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Nabriva.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: September 23, 2019

Respectfully submitted,

/s/ Omar Jafri

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